

### **REMARKS**

Please reconsider the application in view of the foregoing amendments and the following remarks. Applicants thank the Examiner for indicating that claim 16 is allowed and that claim 18 contains allowable subject matter. Applicants also thank the Examiner for the courtesies extended during the Examiner Interviews of August 5, 2004, August 17, 2004, and August 27, 2004.

#### **Examiner Interviews**

An Examiner Interview was conducted on August 5, 2004. During the interview, Applicants noted that the Fischell reference cited in the then-outstanding office action was previously considered during the prosecution of a related application that issued as U.S. Patent No. 6,554,809.

The Examiner suggested amendment of the independent claims to specify that the cutting surface is "sharp." Furthermore, the Examiner indicated that specifying that the cutting surface extended along a bottom surface of the needle would also be helpful. The claims have been amended accordingly.

An Examiner Interview was initiated by the Examiner on August 17, 2004. During the Interview, the Examiner indicated that, after speaking with her supervisor, she believed that he was inclined to allow the application as amended by the Applicants' after-final response, filed August 9, 2004, with some minor changes. These changes included the removal of the term "adapted" from the "adapted to" language embodied in various claims. These amendments were authorized by Applicants' representative, and the Examiner indicated that a Notice of Allowance should

be forthcoming. These amendments are also included in this Submission.

An Examiner interview was initiated by the Examiner on August 27, 2004. During this Interview, the Examiner advised Applicants' representative that, although she had intended to allow the application, new prior art had come to her attention that would not permit her to issue a Notice of Allowance. This prior art, identified as U.S. Patent No. 4,826,492, issued to Magasi ("Magasi") was discussed and Applicants' representative pointed out what were believed to be substantial differences between Magasi's disclosure, and the instant claims. The Examiner stated that any such arguments would need to be formally submitted. Accordingly, these arguments, and a discussion of the Magasi reference, are included with this Submission.

### **Disposition of Claims**

Claims 1-21 are pending in this application. Claims 1, 8, 16, and 17 are independent. The remaining claims depend, directly or indirectly, from these claims.

### **Claim Amendments**

Claim 18 is amended in this response to incorporate the limitations of the independent claim from which it depends. Accordingly, this claim is now in independent claim format. No new matter has been added by way of this amendment, support for which may be found at least in the original dependent claim.

Independent claims 1, 8, and 17 are amended in this response to clarify that the cutting surface is sharp, and extends along a portion of the bottom surface of the needle, per the Examiner Interview of August 5, 2004. No new matter has been added by way of

these amendments, support for which may be found at least in Figs. 5 and 5A – 5C of the application.

Claims 3, 5, 8, 11, 17, 19, and 20 are amended to remove the term “adapted” from the “adapted to” language included therein, per the Examiner’s suggestion in the Examiner Interview of August 17, 2004. No new matter has been added by way of these amendments, support for which may be found at least in these same claims as originally filed.

### **Objections**

Claim 18 is objected to as being dependent upon a rejected base claim. Claim 18 is amended in this response to incorporate the limitations of the independent claim from which it depends. Accordingly, withdrawal of this objection is respectfully requested.

### **Rejection under 35 U.S.C § 102**

Claims 1-6, 8-10, 11-15, 17, 20, and 21 stand rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 4,141,365, issued to Fischell et al. (“Fischell”). Independent claims 1, 8, and 17 are amended in this reply to clarify that the cutting surface extends along a portion of the bottom surface of the distal end of the needle. To the extent this rejection may apply to the amended claims, it is respectfully traversed.

Independent claims 1, 8, 16, and 17 relate to a needle comprising a hollow shaft having opposed distal and proximal ends. At the top of the distal end is the opening of a lumen and at the bottom of the distal end is a sharpened cutting surface that extends along a portion of the bottom surface. Such an embodiment advantageously facilitates insertion

into an interspinal space, while decreasing the likelihood of trauma to the spinal fibers as the needle is inserted.

In contrast to such an embodiment, Fischell discloses a tissue stimulation apparatus having a sharpened, *oblique point* 14 (Col. 3, ll. 56-57). The Fischell apparatus may also have a point 14 that is upwardly curved (Col. 5, ll. 33-34). The point 14 of the apparatus according to Fischell, similar to that of a typical prior art medical needle, is designed to pierce tissue, in contrast to the separating/cutting design of the instant invention as shown in Figs. 1 and 5.

Although Fig. 1a of Fitchell includes a reference number (14) that points to a bottom surface of the tip of the needle, Applicants assert that this is done simply to indicate the point of the needle, and not to specify a cutting surface. Throughout the specification, Fischell refers only to a **point** and makes no reference at all to cutting, or a cutting surface.

Furthermore, the Fischell device is designed to penetrate in an upwardly direction as shown in Figs. 2, 6, 7, and 8 and in accordance with the methods disclosed by Fischell. Such an upwardly-oriented cutting point configuration is clearly distinct from a cutting surface (sharpened edge) extending along a *bottom portion* of a needle. Fischell neither discloses nor suggests a *cutting surface* on a bottom surface of a needle having an opening on an upper surface of the same distal end.

In view of the above, independent claims 1, 8, 16, and 17, as amended, are patentable over Fischell. Claims 2-6, 9, 10, 11-15, 20, and 21, which depend from amended claims 1, 8, 16, and 17 respectively, are similarly patentable. Therefore, withdrawal of this rejection is respectfully requested.

### **Rejections under 35 U.S.C § 103**

Claim 7 stands rejected under 35 U.S.C. § 103 as being obvious over Fischell. This rejection is respectfully traversed.

Claim 7 depends from amended independent claim 1 and is therefore patentable over Fischell for at least the same reasons discussed above with respect to amended claim 1. In particular, Fischell neither discloses nor suggests a sharpened cutting surface located on the bottom of the distal end of a hollow shaft having an opening at its upper distal end, as recited in claim 1. Accordingly, withdrawal of this rejection is respectfully requested.

Claim 19 stands rejected under 35 U.S.C. § 103 as being obvious over Fischell in view of U.S. Patent No. 4,945,895, issued to Takai et al. ("Takai"). This rejection is respectfully traversed.

Claim 19 depends from amended independent claim 17 and is therefore patentable over Fischell for at least the same reasons discussed above with respect to amended claim 17. In particular, Fischell neither discloses nor suggests a sharpened cutting surface located along a bottom portion of the distal end of a hollow shaft having an opening at its upper distal end, as recited in claim 17. Takai also fails to disclose or suggest such a cutting surface and configuration as recited in claim 17. Therefore, claim 19 is patentable over Fischell and Takai. Accordingly, withdrawal of this rejection is respectfully requested.

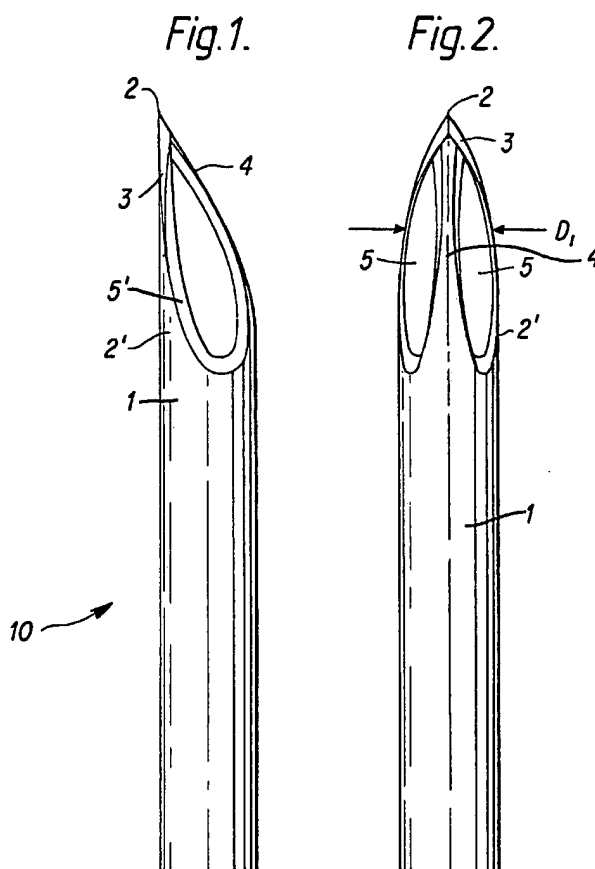
### **The Magasi Reference**

Magasi was cited by the Examiner in the Examiner Interview of August 27, 2004,

as being relevant to the pending claims of the current application. Although Magasi has not been formally cited in an office action, Applicants wish to address this reference at this time in order to expedite prosecution of the instant application.

As shown in Figures 1 and 2, Magasi is directed to a needle-type medical probe having a dual-aperture configuration (apertures shown at 5) with a displacement surface 4 between the two apertures 5. The displacement surface 4 lifts and stretches a punctured membrane onto the shaft 1 of the needle. Note that the displacement surface 4 is not a “sharpened edge” nor does it extend along a portion of the *bottom* of the needle’s shaft. A puncturing tip 2 and cutting edges 3 pierce and cut as the needle is inserted.

In contrast to the instant claims as amended, Magasi fails to disclose or suggest either (1) a sharpened cutting surface extending along a portion of the bottom of the needle’s shaft, or (2) an opening into the lumen, *located at the top of the shaft* (opposite the cutting surface). For at least these two reasons, the instant claims are patentable over Magasi.



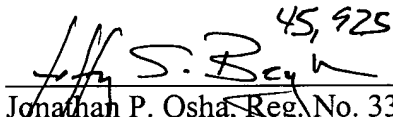
Figures 1 and 2 of Magasi

**Conclusion**

Applicants believe this reply is fully responsive to all outstanding issues and places this application in condition for allowance. If this belief is incorrect, or other issues arise, the Examiner is encouraged to contact the undersigned or his associates at the telephone number listed below. Please apply any charges not covered, or any credits, to Deposit Account 50-0591 (Reference Number 06570.002002).

Respectfully submitted,

Date: 10/6/04

  
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